REMARKS

Reconsideration in view of the following remarks is respectfully requested. Amendments to claims 80 and 82 and new claim 80 have been proposed. In addition, an amendment to the specification has been proposed. The amendment to the specification incorporates Table 1, which is found in U.S. Application Serial No. 08/367,395, filed December 30, 1994, now U.S. Patent No. 6,046,037, which was incorporated by reference.

Interview Request

Applicants request an interview so that the remaining issues in this case may be discussed. The Examiner is requested to phone the undersigned at (415) 268-6846 to set up a telephonic interview in this case.

35 U.S.C. § 112, Second Paragraph

Claims 80 and 82 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite as failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner has reiterated the rejections from the previous Office Action mailed 8/29/02. Specifically, the previous Office Action provides that:

> "Claim 80 is vague and indefinite for recitation of "protection protein", the intended metes and bounds of the protein are not defined. Is a ricin protein intended? The term "derived' in claim 80 is a relative term, with renders the claim indefinite. The term "derived" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The instant case, the definition of derivation has many meaning, therefore, the claim is considered as indefinite. In addition the intended metes and bounds of the protein that is "derived" from a "polyimmunoglobulin receptor" are not defined. Moreover, the intended polyimmunoglobulin receptor is not defined. This affects claims 82."

"Claim 82 is vague and indefinite for recitation of "plant produced", what is the intended plant. Is cacti intended?"

"Claim 82 is rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP §2172.01. The omitted steps are: transformation, types of plant i.e., transgenic or non, the conditions that would permit the production of antibody should be stated."

Claim 80

Applicants disagree that the recitation of "protection protein", "derived", and "polyimmunoglobulin receptor" in claim 80 is vague. The specification clearly describes the scope of the terms. However, in order to facilitate prosecution in this case Applicants have amended the pending claims, without prejudice or disclaimer, to recite "a protection protein wherein the protection protein contains a portion of a polyimmunoglobulin receptor". With the amendment, the claim no longer recites "derived" and clearly indicates the definition of a protection protein. Furthermore, amending Table 1 gives clear definition of what constitutes a polyimmunoglobulin receptor. One of skill in the art is reasonably apprised of what constitutes a polyimmunoglobulin receptor through Table 1 and the rest of the specification.

Claim 82

Applicants disagree that the recitation of "plant produced" is indefinite. However, in order to facilitate prosecution in this case Applicants have amended the pending claims, without prejudice or disclaimer, to recite "isolated from a plant". The Examiner has asserted that the nature of the glycosylation of the immunoglobulin produced will vary depending upon what plant the immunoglobulin is produced from and that the varying glycosylation state will alter the characteristics of the immunoglobulin. The Examiner has asserted that therefore the type of plant must be defined in order for one of skill in the art to understand the metes and bounds of the claimed invention. The Examiner has further asserted that essential steps have been omitted.

Applicants respectfully disagree with the Examiner's assertion that different plants will produce different patterns of glycosylation on a given immunoglobulin. The Examiner has provided no support for this assertion. Applicants are unaware of the source of such assertion. Applicants respectfully traverse and request that the Examiner provide references that demonstrate different plants producing the same immunoglobulin with different patterns of glycosylation so that Applicants can better understand the Examiner's argument. *See*, MPEP § 2144.03 "If the applicant traverses such an assertion the examiner should cite a reference in support of his or her position."

Even if different plants produced different glycosylation on an immunoglobulin, such is irrelevant. The scope of the claim is not limited to an immunoglobulin with any particular function. Thus it is irrelevant that a particular immunoglobulin produced in different plants may have different levels of activity. The claims are drawn to a composition with two elements, an immunoglobulin and a protection protein. The protection protein, as discussed in the previous response mailed February 28, 2003, protects the immunoglobulin. This protection is not based upon the particular binding activity of the immunoglobulin. Thus, one of skill in the art will recognize that the metes and bounds of the claims are to any plant.

Applicants respectfully disagree with the Examiner's assertion that the essential steps have been omitted. The Examiner maintains that the claims must recite transformation, types of plant *i.e.*, transgenic or non, and the conditions that would permit the production of antibody. However, all these steps are not essential to the claimed invention. All that matters is that the protection protein and the immunoglobulin are together in a composition isolated from a plant. The steps cited by the Examiner are routine steps that one of ordinary skill in the art would select as appropriate.

In light of the above, Applicants submit that the claims meet the requirements of 35 U.S.C. § 112, second paragraph, and respectfully request that the rejection be withdrawn.

Statutory Double Patenting Rejection

Claims 80 and 82 stand rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1, 12, 13, and 29 of prior U.S. Patent No. 6,303,341 B1 ('341 patent).

The standard for determining whether a statutory basis for a double patenting rejection under 35 U.S.C. § 101 exists is whether the same invention is being claimed twice, wherein "same invention" means identical subject matter. *See,* MPEP 804-IIA. A reliable test for double patenting under 35 U.S.C. § 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim of the patent. *See,* MPEP 804-IIA (citing *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

As stated in the response mailed February 28, 2003, claims 80 and 82 are not claiming the "same invention" as claims 1, 12, 13, and 29 of the '341 patent since claims 80 and 82 could be literally infringed without literally infringing the '341 patent claims. The Examiner has asserted that all possible permutations are present in the '341 patent claims. Applicants respectfully disagree. Applicants only need analyze the scope of the independent claim 1. The dependent claims add limitations and are therefore narrower. It would be impossible for a dependent claim to read on an embodiment while the independent claim does not read on such an embodiment. As discussed in the response mailed February 28, 2003, claim 80 reads on a protection protein that is associated with an immunoglobulin derived light chain with no heavy chain. Claim 1 of the '341 patent does not read on such a complex because it lacks the

immunoglobulin derived heavy chain. While claim 2 of the '341 patent does add the limitation of an immunoglobulin derived light chain in the complex, claim 2 is dependent upon claim 1, so claim 2 still requires that the complex have an immunoglobulin derived heavy chain.

If the Examiner still believes that the claims in the '341 patent read upon a protection protein that is associated with an immunoglobulin derived light chain with no heavy chain, Applicants respectfully request the Examiner to identify specifically the claim in the '341 patent that covers such a complex. Otherwise, Applicants respectfully request that the Examiner withdraw the objection.

Rejections Under 35 U.S.C. § 102(b)

The following claims stand rejected under 35 U.S.C. § 102(b): A) claims 80 and 82 as being anticipated by Lehner *et al.* (WO 88/06455); B) claim 80 as being anticipated by Lehner *et al.* (U.S. 4,594,244); and C) claim 80 as being anticipated by Schlom.

Applicants submit that the claim(s) under each Section 102 rejection are not anticipated. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See* MPEP § 2131 (*citing Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

As further elucidated below, none of the cited art describes or suggests a protection protein derived from a polyimmunoglobulin receptor.

Lehner *et al.* (WO 88/06455)

Lehner *et al.* ('455 patent) teach an antibody specific for *S. sobrinus* serotype d and methods for making the antibody. The *S. sobrinus* serotype d antibody, in comparison to

antibody raised against *S. mutans* serotype c, are cross-reactive with most other *S. sobrinus/S. mutans* serotypes found in the oral cavity. In use, the antibodies are topically applied to prevent dental carries. No where in the reference do Lehner *et al.* describe a protection protein derived from a polyimmunoglobulin receptor.

The Examiner has asserted that Applicants have pointed out that the product disclosed by Lehner *et al.* is capable of doing the same function as Applicants' own claimed product and is therefore anticipatory. Applicants respectfully disagree. As discussed above, the claims do not cover an immunoglobulin with a particular function. The claims cover a product with two elements, a protection protein and an immunoglobulin. Lehner *et al.* teach an immunoglobulin by itself. Lehner *et al.* do not teach a protection protein. Furthermore, the protection protein provides a function that is not found in the monoclonal antibody taught by Lehner *et al.* Example 9 in the specification demonstrates that the protection protein does indeed provide a protective function that is not found with an immunoglobulin alone. Example 9 compares a plant extract with an IgG1 immunoglobulin with a plant extract with an immunoglobulin with a protection protein. The time course with ELISA demonstrates that the protection protein keeps the immunoglobulin from being digested by proteases. After 12 hours, the IgG1 immunoglobulin is undetectable because it has been completely digested whereas ~90% of the immunoglobulin with the protection protein still remains. Thus, clearly Lehner *et al.* fail to teach a protection protein, and the immunoglobulin by itself lacks the protective function of the protective function.

Based on the foregoing, the '455 patent does not describe a limitation of claims 80 and 82, specifically, a protection protein derived from a pIgR. Consequently, the requirements under 35 U.S.C. § 102(b) have not been met, and withdrawal of the rejection is respectfully requested.

Lehner *et al.* (U.S. 4,594,244)

Lehner *et al.* ('244 patent) describe an antigenic material useful for making an antibody vaccine. The antigenic material is obtained from antigen I/II isolated from *S. mutans.* The vaccine prepared from this antigenic material is then administered parenterally or topically to the gums.

Similar to the '455 patent, the '244 patent does not describe all the elements of claim 80, specifically, a protection protein derived from a polyimmunoglobulin receptor.

Withdrawal of the rejection under 35 U.S.C. § 102 (b) is respectfully requested on this basis.

Schlom

Schlom teaches a monoclonal antibody for treating gastrointestinal cancer. The antibody may be conjugated to a label that allows detection of the tumor, or to a therapeutic agent. Conjugation to a protein, particularly a protein derived from a pIgR, that "protects" it from degradation and denaturation is not described.

The Examiner has asserted that the antibody in Schlom will bind to a pIgR and thus possess all the claim limitations. Applicants respectfully traverse. However, in order to facilitate prosecution in this case Applicants have amended the pending claims, without prejudice or disclaimer, to recite "an isolated immunoglobulin". Even if, *assuming arguendo*, the immunoglobulin of Schlom binds to a pIgR, Schlom does not teach an isolated immunoglobulin with a protection protein. If the immunoglobulin does indeed bind to a pIgR, the immunoglobulin with the pIgR is not isolated. Rather, it is in an organism.

Thus, the cited reference does not teach or suggest all the claim limitations under U.S.C. § 102(b). Accordingly, withdrawal of the rejection is respectfully requested.

Rejection Under 35 U.S.C. § 102(e)

Claim 80 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Lehner *et al.* 5,854,402).

Applicants disagree that claim 80 is anticipated by Lehner et al. ('402 patent). The '402 patent is a continuation application of WO 88/06455, and thus contains the same specification. As discussed above, WO 88/06455 does not teach a protection protein derived from a polyimmunoglobulin receptor. Because a limitation of the claims is missing, a rejection under 35 U.S.C. § 102(e) is improper. Withdrawal of the rejection is respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Claim 82 stands rejected under 35 U.S.C. § 103(a) as being allegedly obvious over Lehner *et al.* (WO 88/06455), in view of Hiatt *et al.* (U.S. Patent No. 5,202,422). The Examiner has asserted that the pIgR is a mere design choice.

Applicants respectfully remind the Examiner that in order to properly establish a *prima facie* case of obviousness, three basic criteria must be met, one of which is that the prior art reference (or references combined) must teach or suggest all claim limitations. *See* MPEP 2143.

As discussed above, Lehner *et al.* (WO 88/06455) do not describe an immunoglobulin having a protection protein derived from pIgR. Hiatt *et al.* describe an antibody made in a plant but do not cure this defect because the antibody is not associated with a protection protein. Thus, the references combined do not meet the requirements of Section 103. Again, Applicants stress that the invention

claimed is not to a particular immunoglobulin. The claimed invention is the combination of an immunoglobulin and a protection protein. Thus, the choice of protection protein is not a mere design choice – it is novel and inventive way to protect an immunoglobulin.

In view of the above arguments, Applicants respectfully submit that the grounds for rejection under 35 U.S.C. § 103 have clearly been overcome and request that the rejection be withdrawn.

SUMMARY

Applicants have responded to each matter of substance raised in this Office Action and believe that the case is in condition for allowance. Should the Examiner have any requests, questions, or suggestions, he is invited to contact the Applicants' representative at the number listed below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 415142000302.

Respectfully submitted,

Dated: May 19, 2003

By: 

Otis Littlefield
Registration No. 48,751

Morrison & Foerster LLP
425 Market St
San Francisco, California 94105-2482
Telephone: (415) 268-6846
Facsimile: (415) 268-7522